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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,144	07/19/2000	Ulrich Mohr	29089/34670A	1600

7590

02/11/2003

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EXAMINER

SANDALS, WILLIAM O

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 02/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/619,144

Applicant(s)
Mohr et al.

Examiner
William Sandals

Art Unit
1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 15, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-27, and 32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-27, and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on Nov 15, 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. The amendment of Paper 15, filed November 15, 2002 has been entered. Claims 1 and 11 have been amended. Claim 2 has been cancelled. New claim 32 has been entered. Claims 1, 3-27 and 32 are pending.
2. Amendments to the claims in Paper No. 15 have overcome the rejections of the claims under 35 USC 102 in the previous office action, and the rejections are withdrawn.
3. Amendments to the claims in Paper No. 15 have overcome the rejection of the claims under 35 USC 103 in the previous office action, and the rejection is withdrawn.
4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**
5. Applicant's arguments with respect to claims 1 and 3-27 have been considered but are moot in view of the new ground(s) of rejection. Response to the arguments as they may pertain to the newly made rejection below are contained in the rejection.

Drawings

6. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on November 15, 2002 have been approved. A proper drawing correction or corrected drawings

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are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 3-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites at the last line, "homogeneously be exposed to gases, aerosols and particulate matter. The word "homogeneously" may be broadly interpreted to apply to gases and aerosols, since the laws of diffusion provide for a homogeneous dispersion of gas and aerosol droplets. However, no specific language in the originally filed claims or specification are found to support the "homogeneous" exposure to particulates. Teachings on how to effect "homogeneous" exposure regarding particulates within the culture device are not found in the originally filed claims or specification. The amendment of Paper No. 15 does not recite where support for the amendment may be found in the originally filed claims and specification. A "homogeneous" exposure to particulates requires some particular means to bring this about. Thus, "homogeneous" exposure to particulates does not follow from the

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teachings of the instant claims and specification. Therefore, the claimed "homogeneous" exposure to particulates is new matter.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1 and 3-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 1 recites the limitation "the cultured cells" in line 13. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1, 3-27 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,424,209 (Kearney) in view of SU 734281B (Pankratov et al.) (of record in the first office action as Kolodii et al.), JP 402 119772 (Hamazaki) and GB 2314343A (Liau), (all of record).

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The claims are drawn to a culturing device comprising one or more culture container(s) which contains a horizontal cell culture insert, a culture medium supply and discharge mechanism connected to the culture container. The device comprises a culture medium level sensor, the level sensor controls the supply mechanism, where the culture medium can submerge the cell culture insert or provide a basal culture medium condition permitting homogeneous exposure to gases, aerosols and particulates on the surface of the cell culture insert. The supply mechanism may be connected to the culture container by one or more tubings. There may multiple containers in a horizontal plane. The level sensor may be attached to a riser. The level sensor may be adjustable. The level sensor may be a photoelectric sensor. The culture container and attachments may be sterilizable, which may be made of glass or silicone. The culture container may be temperature controlled. The culture container may be supplied with a gas source. The culture container may have a sealed exterior housing. The operation of the device may be controlled by a programmable controller.

Kearney teaches at the summary at column 4 bridging to column 6, column 9, lines 37-50 and from column 56 bridging to column 10, line 45, column 16, lines 1-68, column 19, lines 45-49, column 21, lines 15-26, and the claims, a culturing device comprising one or more culture container(s) which contains a horizontal cell culture insert, a culture medium supply and discharge mechanism connected to the culture container. The supply mechanism may be connected to the culture container by one of more tubings. There may multiple containers in a horizontal plane. The culture container and attachments may be sterilizable, which may be made

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of glass or silicone. The culture container may be temperature controlled. The culture container may be supplied with a gas source. The culture container may have a sealed exterior housing. The operation of the device may be controlled by a programmable controller.

Kearney did not teach a culture medium level sensor, nor the provision for a basal medium supply condition for cells in the culture container.

Pankratov et al. teach at page 5 of the translation, a culture device comprising two culture containers connected to a culture medium supply. The culture medium is adjusted in the culture containers by a common tubing, whereby the culture medium level in the culture container is alternately submerges the cells in the culture device and drops below the cells in the culture device (basal medium supply condition). A level sensor is used to detect the level of the culture medium in the culture container. Pankratov et al. teach the desirable and beneficial cell growth advantage of changing the level of the culture medium to a submerged condition and a low culture medium level to provide periodic exposure of the cells to gas in the culture chamber.

Hamazaki teaches at pages 3-6 and at pages 12-13 a culture device comprising one or more culture containers with a programmably controlled culture medium supply. The device comprises an adjustable photoelectric level sensor, a gas supply and a temperature controlling mechanism. Hamazaki teaches the desirable and beneficial cell growth advantage of changing the level of the culture medium to a submerged condition and a low culture medium level to provide periodic exposure of the cells to gas in the culture chamber.

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Liau teaches at the abstract, pages 5-7 and at the claims, a culture device comprising one or more culture containers with a programmably controlled culture medium supply. The device comprises an adjustable photoelectric level sensor, a gas supply and a temperature controlling mechanism. Liau teaches the desirable and beneficial cell growth advantage of changing the level of the culture medium to a submerged condition and a low culture medium level to provide periodic exposure of the cells to gas in the culture chamber.

It would have been prima facie obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Kearney with Pankratov et al., Hamazaki and Liau to produce the instant claimed invention because each of Kearney, Pankratov et al., Hamazaki and Liau teach a culture device comprising one or more culture containers with a programmably controlled culture medium supply. The teachings of Hamazaki make obvious the use of a photoelectric level sensor for use controlling the level of the culture medium in the culture device.

One of ordinary skill in the art would have been motivated to combine the teachings of Kearney with Pankratov et al., Hamazaki and Liau to produce the instant claimed invention because each of Pankratov et al., Hamazaki and Liau teach the desirable and beneficial cell growth advantage of changing the level of the culture medium to a submerged condition and a low culture medium level to provide exposure of the cells to gas in the culture chamber. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the

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producing the instant claimed invention given the teachings of Kearney, Pankratov et al., Hamazaki and Liao.

Response to Arguments

14. Arguments set forth in Paper No. 15 assert that the culture device of Liao has the cells in a vertical orientation, making the device of Liao “not well suited” to “homogeneous exposure” to particulates, nor to the “basal culture medium supply conditions”.

Liao teaches the advantageous exposure of cells in the culture device to gas. The teachings of Liao are not relied upon for the limitation argued above, making the argument moot.

15. Arguments set forth in Paper No. 15 assert that Kolodii et al. (herein referred to as Pankratov et al.) does not teach removable horizontal inserts.

Pankratov et al. is not relied upon for teachings of removable horizontal inserts, making the argument moot.

16. Arguments set forth in Paper No. 15 assert that Kearney does not teach a cell culture insert, and the device of Kearney is not suited to basal culture conditions.

Kearney teaches at column 21, lines 15-33 that the culture surface may be a slide of coverslip. Kearney teaches at column 20, lines 51-52 that the cells can be removed from the system. Therefore, the culture slides or coverslips of the system are removable inserts. Kearney is cited above as not teaching the variable level control of cell culture medium.

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Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.
Examiner
February 5, 2003


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SUPERVISORY PATENT EXAMINER
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